

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application No. 10/558,159

Applicant: JAMIL et al.

Filed: November 22, 2005

TC/AU:

Examiner:

Docket No.: 239615

Customer No.: 23460

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that any reference listed thereon is prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that they represent art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that the references are not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### Copies of the References

- ☐ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☒ Copies of U.S. patents and U.S. patent publications that are listed on the accompanying Form 1449 are not enclosed herewith. Copies of other references identified on the accompanying Form 1449 are enclosed herewith.

- ☒ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (CHECK ONE)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

#### Statement under § 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

#### Statement under § 1.704(d)

- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).  
☐ The **IDS Fee of \$180** under § 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$180.00.  
☐ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)


**Instructions as to Overpayment**

- ☒ Credit Account No. 12-1216.  
☐ Refund.

Respectfully submitted,

M. Daniel Hefner, Registration No. 41,826  
**LEYDIG, VOIT & MAYER, LTD.**  
Two Prudential Plaza, Suite 4900  
180 North Stetson  
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(312) 616-5600 (telephone)  
(312) 616-5700 (facsimile)

Date: May 18, 2006

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/558,159
				Filing Date	November 22, 2005
				First Named Inventor	JAMIL, Haris
				Group Art Unit	
Examiner Name					
Sheet	1	of	6	Attorney Docket Number	239615


U.S. PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date, if appropriate MM-DD-YYYY
		Document Number	Kind Code			
	AA	US- 4,774,085		09-27-1988	Fidler	
	AB	US- 4,952,408		08-28-1990	Rahman	
	AC	US- 5,424,073		06-13-1995	Rahman et al.	
	AD	US- 5,648,090		07-15-1997	Rahman et al.	
	AE	US- 5,744,460		04-28-1998	Muller et al.	
	AF	US- 6,056,973		05-02-2000	Allen et al.	
	AG	US- 6,090,955		07-18-2000	Reszka et al.	
	AH	US- 6,126,965		10-03-2000	Kasid et al.	
	AI	US- 6,146,659		11-14-2000	Rahman	
	AJ	US- 6,333,314		12-25-2001	Kasid et al.	
	AK	US- 6,461,637		10-08-2002	Rahman	
	AL	US- 6,469,058		10-22-2002	Grove et al.	
	AM	US- 6,559,129		05-06-2003	Kasid et al.	
	AN	US- 2003/0035830	A1	02-20-2003	Rahman et al.	
	AO	US- 2003/0215489	A1	11-20-2003	Kasid et al.	
	AP	US- 2003/0215492	A1	11-20-2003	Ahmad et al.	
	AQ	US- 2003/0219476	A1	11-27-2003	Ahmad et al.	
	AR	US- 2003/0225023	A1	12-04-2003	Kasid et al.	
	AS	US- 2003/0228317	A1	12-11-2003	Gokhale et al.	
	AT	US- 2003/0229040	A1	12-11-2003	Kasid et al.	
	AU	US- 2004/0005603	A1	01-08-2004	Kasid et al.	
	AV	US- 2004/0082771	A1	04-29-2004	Kasid et al.	
	AW	US- 2004/0106571	A1	06-03-2004	Kasid et al.	
	AX	US- 2004/0115714	A1	06-17-2004	Kasid et al.	
	AY	US- 2004/0248218	A1	12-09-2004	Kasid et al.	

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

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Examiner Signature		Date Considered	
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<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

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		Document Number	Kind Code			
	AZ	US- 2005/0002918	A1	01-06-2005	Strauss et al.	
	BA	US- 2005/0019387	A1	01-27-2005	Rahman et al.	
	BB	US- 2005/0148528	A1	07-07-2005	Gately	
	BC	US- 2005/0153297	A1	07-14-2005	Ahmad et al.	
	BD	US- 2005/0181037	A1	08-18-2005	Ahmad et al.	
	BE	US- 2005/0202074	A1	09-15-2005	Rahman	
	BF	US- 2005/0238706	A1	10-27-2005	Ahmad et al.	
	BG	US- 2005/0249795	A1	11-10-2005	Zhang et al.	
	BH	US- 2005/0266068	A1	12-01-2005	Ahmad et al.	
	BI	US- 2005/0277611	A1	12-15-2005	Ahmad et al.	
	BJ	US- 09/354,109			Kasid et al.	07-15-1999
	BK	US- 09/930,283			Kasid et al.	08-16-2001
	BL	US- 10/056,210			Kasid et al.	01-28-2002
	BM	US- 10/239,598			Rahman	10-25-2000
	BN	US- 10/680,313			Kasid et al.	10-06-2003
	BO	US- 10/786,866			Zhang et al.	02-24-2004
	BP	US- 10/842,189			Strauss et al.	05-09-2004
	BQ	US- 11/010,158			Kasid et al.	12-10-2004
	BR	US- 11/061,044			Ahmad et al.	02-18-2005
	BS	US- 11/105,970			Ahmad et al.	04-14-2005
	BT	US- 11/106,406			Ahmad et al.	04-14-2005
	BU	US- 11/177,194			Ahmad et al.	07-08-2005
	BV	US- 11/196,123			Zhang et al.	08-03-2005
	BW	US- 11/201,810			Bhamidipati et al.	08-11-2005
	BX	US- 11/287,530			Jamil et al.	11-22-2005

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

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		Document Number	Kind Code			
	BY	US- 60/041,192			Kasid et al.	03-21-1997
	BZ	US- 60/165,236			Puri et al.	11-11-1999
	CA	US- 60/229,842			Puri et al.	08-31-2000
	CB	US- 60/241,069			Rahman et al.	10-16-2000
	CC	US- 60/247,306			Rahman et al.	11-09-2000
	CD	US- 60/264,062			Kumar et al.	01-26-2001
	CE	US- 60/281,779			Kasid et al.	04-06-2001
	CF	US- 60/281,780			Kasid et al.	04-06-2001
	CG	US- 60/281,785			Kasid	04-06-2001
	CH	US- 60/281,796			Kasid et al.	04-06-2001
	CI	US- 60/294,285			Rahman et al.	05-29-2001
	CJ	US- 60/314,959			Rahman et al.	08-24-2001
	CK	US- 60/332,477			Strauss et al.	11-09-2001
	CL	US- 60/371,116			Kasid et al.	04-10-2002
	CM	US- 60/371,126			Kasid et al.	04-10-2002
	CN	US- 60/382,031			Gokhale et al.	05-22-2002
	CO	US- 60/382,411			Gately	05-20-2002
	CP	US- 60/383,340			Ahmad et al.	05-24-2002
	CQ	US- 60/384,222			Ahmad et al.	05-29-2002
	CR	US- 60/404,668			Rahman et al.	08-20-2002
	CS	US- 60/405,378			Zhang et al.	08-23-2002
	CT	US- 60/419,277			Ahmad et al.	10-16-2002
	CU	US- 60/429,285			Ahmad et al.	11-26-2002
	CV	US- 60/438,659			Ahmad et al.	01-07-2003
	CW	US- 60/444,958			Zhang et al.	02-03-2003

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	CX	US- 60/446,895			Bhamidipati et al.	02-11-2003
	CY	US- 60/457,898			Gately et al.	03-26-2003
	CZ	US- 60/467,331			Ahmad et al.	05-02-2003
	DA	US- 60/472,664			Jamil et al.	05-22-2003
	DB	US- 60/480,669			Jamil et al.	06-23-2003
	DC	US- 60/495,260			Jamil et al.	08-13-2003
	DD	US- 60/514,658			Ahmad et al.	10-27-2003
	DE	US- 60/535,042			Ahmad et al.	01-07-2004
	DF	US- 60/556,843			Ahmad et al.	03-27-2004
	DG	US- 60/557,232			Ahmad et al.	03-29-2004
	DH	US- 60/577,414			Hussey et al.	06-05-2004
	DI	US- 60/583,833			Ahmad et al.	06-29-2004

FOREIGN PATENT DOCUMENTS									
Examiner Initials <sup>1</sup>	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Translation Provided?	
		Office	Number	Kind Code				Yes	No
	DJ	DE	39 36 328	A	05-02-1991	Schering AG			
	DK	DE	101 31 796	A	01-16-2003	Beiersdorf AG			
	DL	WO	93/18751	A	09-30-1993	Georgetown University			
	DM	WO	98/43095	A	10-01-1998	Georgetown University			
	DN	WO	00/01366	A	01-13-2000	NeoPharm, Inc.			
	DO	WO	01/34130	A	05-17-2001	Boulikas			
	DP	WO	01/34116	A	05-17-2001	P.N. Gerolymatos S.A.			
	DQ	WO	01/70220	A	09-27-2001	NeoPharm, Inc.			
	DR	WO	01/95946	A	12-20-2001	Transgene S.A.			


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		Office	Number	Kind Code				Yes	No
	DS	WO	02/32400	A	04-25-2002	NeoPharm, Inc.			
	DT	WO	02/058622	A	08-01-2002	NeoPharm, Inc.			
	DU	WO	02/059337	C2	08-01-2002	Georgetown Univ. School of Medicine			
	DV	WO	02/081639	A	10-17-2002	Georgetown Univ.			
	DW	WO	02/081640	A	10-17-2002	Georgetown Univ.			
	DX	WO	02/081641	A	10-17-2002	Georgetown Univ.			
	DY	WO	02/081642	A	10-17-2002	Georgetown Univ.			
	DZ	WO	03/018018	A	03-06-2003	NeoPharm, Inc.			
	EA	WO	03/030864	A	04-17-2003	NeoPharm, Inc.			
	EB	WO	03/039600	A	05-15-2003	NeoPharm, Inc.			
	EC	WO	03/070221	A	08-28-2003	Georgetown Univ.			
	ED	WO	03/099213	A	12-04-2003	NeoPharm, Inc.			
	EE	WO	03/099830	A	12-04-2003	NeoPharm, Inc.			
	EF	WO	03/102011	A	12-11-2003	NeoPharm, Inc.			
	EG	WO	2004/017940	A	03-04-2004	NeoPharm, Inc.			
	EH	WO	2004/017944	A	03-04-2004	NeoPharm, Inc.			
	EI	WO	2004/035523	A	04-29-2004	NeoPharm, Inc.			
	EJ	WO	2004/039817	A	05-13-2004	NeoPharm, Inc.			
	EK	WO	2004/062569	A	07-29-2004	NeoPharm, Inc.			
	EL	WO	2004/069224	A	08-19-2004	NeoPharm, Inc.			
	EM	WO	2004/071466	A	08-26-2004	NeoPharm, Inc.			
	EN	WO	2004/087758	A	10-14-2004	NeoPharm, Inc.			
	EO	WO	2005/000266	A	01-06-2005	NeoPharm, Inc.			

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	EP	WO	2005/000318	A	01-06-2005	NeoPharm, Inc.			
	EQ	WO	2005/042028	A	05-12-2005	NeoPharm, Inc.			
	ER	WO	2005/067632	A	07-28-2005	NeoPharm, Inc.			

OTHER - NON PATENT LITERATURE DOCUMENTS									
Examiner Initials <sup>1</sup>	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.						Translation Provided?	
								Yes	No
	ES	CAPONIGRO et al., "Raltitrexed/5-fluorouracil-based combination chemotherapy regimens in anticancer therapy," <i>Anti-Cancer Drugs</i> , 12 (6), 489-497 (July 2001).							
	ET	DAMON et al., "Advances in rational combination chemotherapy," <i>Cancer Invest.</i> , 4, 421-444 (1986).							
	EU	LEWIS et al., "Phase I and pharmacokinetic study of irinotecan in combination with raltitrexed," <i>Cancer Chemother. Pharmacol.</i> , 50, 257-265 (2002).							
	EV	PARK, "Liposome-based drug delivery in breast cancer treatment," <i>Breast Cancer Res.</i> , 4 (3), 95-99 (2002).							
	EW	PATHAK et al., "Potentiation of the effect of paclitaxel and carboplatin by antioxidant mixture on human lung cancer H520 cells," <i>J. Am. Coll. Nutr.</i> , 21 (5), 416-421 (2002).							
	EX	RICCI et al., "Gemcitabine plus epirubicin in patients with advanced urothelial carcinoma who are not eligible for platinum-based regimens," <i>Cancer</i> , 95, 1444-1450 (2002).							
	EY	SOCINSKI et al., "Phase II trial of irinotecan, paclitaxel and carboplatin in patients with previously untreated stage IIIB/IV nonsmall cell lung carcinoma," <i>Cancer</i> , 95, 1520-1527 (2002).							
	EZ	THIGPEN, "The role of gemcitabine-based doublets in the management of ovarian carcinoma," <i>Semin. Oncol.</i> , 29 (1 Suppl. 1), 11-16 (2002).							

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature		Date Considered	
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<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.